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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,187	07/09/2001	Benjamin Wolozin	PAN01/002US	6018

21874 7590 07/15/2003  
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/15/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/901,187

Applicant(s)

WOLOZIN ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 and 39-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group XVIII, drawn to a composition of  $Mg^{2+}$  and a peptide of SEQ ID NO: 8 in Paper No. 12 is acknowledged. Claims that correspond to the elected invention are 33-35 and 38.

Applicant is advised that Petition under 37 C.F.R. § 181 (a) (3), filed on November 04, 2002, Paper No. 12, is premature, see 37 C.F.R. § 1.144 and § 1.181. Therefore, the instant petition has been treated as part of traversal of the restriction requirement. The traversal is on the ground(s) that "(D) Claims 33, 34 and 38 are not directed to a composition of  $Mg^{2+}$  and one of twelve peptides" (see page 4, first paragraph of the petition of Paper No. 12), and further, that "[t]he claims reciting the peptides are proper Markush claims because each of the peptides has a common utility as an agent for inhibiting the formation of  $\alpha$ -synuclein aggregates" (middle at page 6). Applicant's arguments have been fully considered and, after further examination of the instant invention, reevaluation of restriction requirements was made. As such, claims 33-38 have been rejoined into one group drawn to a composition comprising  $Mg^{2+}$  and at least one peptide which binds to  $\alpha$ -synuclein and inhibits the aggregation thereof.

Claims 1-32 and 39-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 33-38 are under examination in the instant office action.

***Priority***

2. Priority of the instant application under 35 U.S.C. 119(e) based upon a previously filed provisional applications 60/217,319, filed 07/07/2000 and 60/279,199, filed on 03/28/2001 is acknowledged.

***Drawings***

3. The drawings filed on December 31, 2001 contain figures that are presented in separate panels. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, because Figure 1 is divided into Figures 1A-1B, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

***Specification***

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 33, 34 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 33, 34 and 38 are directed to a composition comprising  $Mg^{2+}$  and at least one peptide which binds to  $\alpha$ -synuclein and inhibits the aggregation thereof. However, the instant specification fails to describe the entire genus of peptides, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a peptide, which has the amino acid sequence of SEQ ID NO: 7, which is shown to bind to  $\alpha$ -synuclein and inhibit the aggregation thereof (page 31-32 of the instant specification) and also the peptides specifically recited on page 13, first paragraph, and in claim 35. The subject matter, which is claimed, is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are compositions comprising at least one peptide, which binds to  $\alpha$ -synuclein and inhibits the aggregation thereof. Thus, the claims are not limited to a composition comprising a peptide with a specific amino acid sequence. The claims only require the peptide to bind to  $\alpha$ -synuclein and inhibit the aggregation thereof. As such, the instant claims depend on a recited property (*i.e.* ability to bind to  $\alpha$ -synuclein and inhibit the aggregation thereof) and cover every conceivable structure (means) for achieving the stated property (result)

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while the specification discloses at most only those known to the inventor. Therefore, there is a lack of guidance and teaching regarding structure and function because there is no explanation regarding a nexus between structure of a peptide and its ability to bind to  $\alpha$ -synuclein and inhibit the aggregation thereof provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus, which are encompassed by the instant claims except for the peptides specifically recited in claim 35. The specification does not provide a complete structure of those peptides that bind to  $\alpha$ -synuclein and inhibit the aggregation thereof. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure or a common structural motif) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Further, the specification fails to provide a representative number of species for the claimed genus (those peptides that bind to  $\alpha$ -synuclein and inhibit the aggregation thereof). Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 34 is indefinite for recitation "NAC portion". A full name of the acronym should be presented at its first appearance.
8. Claims 35-37 are indefinite for being dependent from indefinite claim.

### *Conclusion*

9. Claims 33-38 are rejected. Claims 35-37 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
July 11, 2003

